

IMPACT Registry™

V3.0 Data Collection Form **Interventional Cardiology**



AMERICAN COLLEGE of CARDIOLOGY®

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Data Collection Form V3.0

Interventional Cardiology

IMPACT Registry™

DEMOGRAPHICS

Last Name ²⁰⁰⁰ :		First Name ²⁰¹⁰ :	Middle Name ²⁰²⁰ :
Birth Date ²⁰⁵⁰ : mm / dd / yyyy		SSN ²⁰³⁰ : - -	☐ SSN N/A ²⁰³¹
Patient ID ²⁰⁴⁰ : (auto)		Other ID ²⁰⁴⁵ :	
Sex ²⁰⁶⁰ : ☐ Male ☐ Female		Patient Zip Code ²⁰⁶⁵ : _____	☐ Zip Code N/A ²⁰⁶⁶
Race: (Select all that apply) ☐ White ²⁰⁷⁰ ☐ Black/African American ²⁰⁷¹ ☐ American Indian/Alaskan Native ²⁰⁷³ ☐ Asian ²⁰⁷² ☐ Native Hawaiian/Pacific Islander ²⁰⁷⁴ ☐ Middle Eastern/North African ²⁰⁷⁵			
Hispanic or Latino Ethnicity ²⁰⁷⁶ : ☐ No ☐ Yes			

EPISODE OF CARE

Arrival Date/Time ³⁰⁰¹ : mm / dd / yyyy HH:MM	
Health Insurance ³⁰⁰⁵ : ☐ No ☐ Yes → If Yes, Payment Source ³⁰¹⁰ : ☐ Private health insurance ☐ State-specific plan (non-Medicaid) (Select all that apply) ☐ Medicare (Part A or B) ☐ Medicare Advantage (Part C) ☐ Medicaid ☐ Military health care ☐ Indian Health Service ☐ Non-US insurance → If any Medicare, Medicare Beneficiary Identifier ¹²⁸⁴⁶ : _____	
Research Study ³⁰²⁰ : ☐ No ☐ Yes → If Yes, Study Name ³⁰²⁵ , Patient ID ³⁰³⁰ _____, _____	
IMPACT Pathway ¹⁵⁸³⁶ : ☐ Diagnostic or interventional catheterization ☐ Electrophysiology study with or without ablation (Select all that apply) ☐ Cardiovascular implantable electronic device (CIED)	
Primary Diagnosis ¹⁵⁸³⁵ : <u>Select from dynamic list</u>	

HISTORY AND RISK FACTORS

Genetic Condition ¹⁵¹¹³ : ☐ No ☐ Yes → If Yes, Condition Name ¹⁵⁰⁴⁸ : <u>Select all that apply from list</u>		
CONDITION HISTORY ¹²⁹⁰³	OCCURRENCE ¹⁵⁵¹⁰	
Stroke	☐ No ☐ Yes	
PROCEDURE HISTORY ¹²⁹⁰⁵	OCCURRENCE ¹⁵⁵¹¹	→ IF YES AND WITHIN 30 DAYS
Cardiac catheterization	☐ No ☐ Yes	Procedure ¹⁵⁰³⁸ : _____, _____ ☐ Procedure Not Documented ¹⁵⁸⁵⁶ (or beyond 30 days)
Cardiac surgery	☐ No ☐ Yes	Surgery ¹⁵⁰⁴⁵ : _____, _____ ☐ Surgery Not Documented ¹⁵⁸⁵⁷ (or beyond 30 days)

INFANTS (COMPLETE FOR PATIENTS LESS THAN 1 YEAR OLD)

Gestational Age ¹⁵⁰⁴¹ : _____ Weeks	☐ Gestational Age Not Documented ¹⁵⁸⁴⁶
NEONATES (COMPLETE FOR PATIENTS AGE 30 DAYS OR YOUNGER ONLY)	
Birth Weight ¹⁵⁰⁴⁰ : _____ O kg ☐ g	☐ Not Documented ¹⁵⁸⁴⁵

LAB VISIT (COMPLETE FOR EACH LAB VISIT)

Procedures Performed ¹⁵⁰⁸¹ : (Select all that apply) ☐ Coarctation intervention ☐ Proximal pulmonary artery stenting ☐ Atrial septal defect closure ☐ Transcatheter pulmonary valve replacement ☐ Premature infant patent ductus arteriosus closure ☐ Aortic valvuloplasty ☐ Other non-module intervention (NMI) ☐ Diagnostic catheterization only	
Procedure Room Entry Date/Time ¹⁵⁶⁹⁴ : MM / DD / YYYY HH:MM	Procedure Start Date/Time ⁷⁰⁰⁰ : MM / DD / YYYY HH:MM
Procedure End Date/Time ⁷⁰⁰⁵ : MM / DD / YYYY HH:MM	Procedure Room Exit Date/Time ¹⁵⁶⁹⁵ : MM / DD / YYYY HH:MM



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CONCURRENT CONDITIONS (COMPLETE FOR DIAGNOSTIC OR INTERVENTIONAL CATHETERIZATION LAB VISIT)

Non-Cardiac Comorbidity¹⁵⁸⁸⁵: ☐ No ☐ Yes (At the time of procedure)

Cardiac Comorbidity¹⁵⁸⁸⁸: ☐ No ☐ Yes (At the time of procedure)

Arrhythmia¹⁵⁸⁸³: ☐ No ☐ Yes (Within the last 90 days)

Cardiac Arrest¹⁵⁹⁶⁶: ☐ No ☐ Yes (Within 48 hours)

NON-CARDIAC COMORBIDITY (COMPLETE IF NON-CARDIAC COMORBIDITY¹⁵⁸⁸⁵ = YES)

NON-CARDIAC COMORBIDITY NAME ¹⁵⁸⁸⁶	OCCURRENCE ¹⁵⁸⁸⁷	NON-CARDIAC COMORBIDITY NAME ¹⁵⁸⁸⁶	OCCURRENCE ¹⁵⁸⁸⁷
Chronic lung disease	☐ No ☐ Yes	End stage renal disease	☐ No ☐ Yes
Congenital diaphragmatic hernia	☐ No ☐ Yes	Seizure disorder	☐ No ☐ Yes
Known airway problems	☐ No ☐ Yes	Global developmental delay	☐ No ☐ Yes
Diabetes mellitus	☐ No ☐ Yes	Bleeding disorder	☐ No ☐ Yes
Acute kidney injury	☐ No ☐ Yes	Hypercoagulable state	☐ No ☐ Yes
Chronic renal insufficiency	☐ No ☐ Yes	Sickle cell anemia	☐ No ☐ Yes

CARDIAC COMORBIDITY (COMPLETE IF CARDIAC COMORBIDITY¹⁵⁸⁸⁸ = YES)

CARDIAC COMORBIDITY NAME ¹⁵⁸⁸⁹	OCCURRENCE ¹⁵⁸⁹⁰	CARDIAC COMORBIDITY NAME ¹⁵⁸⁸⁹	OCCURRENCE ¹⁵⁸⁹⁰
Single ventricle	☐ No ☐ Yes	Pulmonary hypertension	☐ No ☐ Yes
1.5 ventricle	☐ No ☐ Yes	Rheumatic heart	☐ No ☐ Yes
L-looped ventricles	☐ No ☐ Yes	Kawasaki disease	☐ No ☐ Yes
Dilated cardiomyopathy	☐ No ☐ Yes	Ischemic cardiomyopathy	☐ No ☐ Yes
Hypertrophic cardiomyopathy	☐ No ☐ Yes	Heart failure	☐ No ☐ Yes
Restrictive cardiomyopathy	☐ No ☐ Yes		

Arrhythmia(s) (COMPLETE IF ARRHYTHMIA¹⁵⁸⁸³ = YES)

→ If Yes, **Arrhythmia(s)**¹⁵⁸⁸⁴: ☐ Atrial fibrillation ☐ Atrial flutter ☐ Supraventricular tachycardia
(Select all that apply) ☐ 1° heart block ☐ 2° heart block (Any) ☐ Complete heart block
☐ Sinus node dysfunction ☐ Ventricular tachycardia ☐ Wolff-Parkinson-White syndrome ☐ Other

PRE-PROCEDURE (COMPLETE FOR EACH LAB VISIT)

Height¹⁵⁰²⁰: _____ O cm ☐ in **Weight**¹⁵⁰²¹: _____ O kg ☐ g

PRE-PROCEDURE MEDICATIONS (WITHIN THE LAST TWO WEEKS)

MEDICATIONS ¹⁵⁰³²	ADMINISTERED ⁶⁹⁹¹		MEDICATIONS ¹⁵⁰³²	ADMINISTERED ⁶⁹⁹¹	
	No	Yes		No	Yes
Angiotensin converting enzyme-Inhibitor (Any)	☐	☐	Antiplatelet (Any)	☐	☐
Angiotensin II receptor blocker (Any)	☐	☐	Beta blockers (Any)	☐	☐
Antiarrhythmic (Any)	☐	☐	Diuretic (Any)	☐	☐
Anticoagulant – DOAC/NOAC	☐	☐	Pulmonary vasodilator (Any)	☐	☐
Anticoagulant - Warfarin	☐	☐	Prostaglandin Infusion	☐	☐

PRE-PROCEDURE DIAGNOSIS

Pre-Procedure Diagnosis Code(s)¹⁵⁰²²: _____, _____, _____

PROCEDURE INFORMATION

Operator's Name, NPI ^{15073, 15074, 15072, 7115, 16237} :		<u>Last, First, Middle, NPI</u>		<u>Last, First, Middle, NPI</u>		<u>Operator Role</u>	
Fellow Operator Name, NPI, Fellowship Training Program ^{15431, 15433, 15434, 15435, 15436} :		<u>Last, First, Middle, NPI</u>					
Procedure Status ¹⁵⁰⁷¹ :	☐ Elective	☐ Urgent	☐ Emergent	☐ Salvage			
Visit Location ¹⁵⁸⁵⁵ :	☐ Outpatient setting	☐ Inpatient non critical care	☐ Inpatient critical care				
Patient Disposition ¹⁵⁰⁸⁰ :	☐ Outpatient care	☐ Admit to inpatient ward	☐ Admit to inpatient ICU	☐ Other			
Anesthesia Type ¹⁵⁹⁹⁹ : ☐ General anesthesia ☐ Moderate sedation ☐ Minimal sedation/anxiolysis/local only							
→If General anesthesia, Anesthesia Time ¹⁶¹⁶⁵ : _____ minutes ☐ Not Documented ¹⁶¹⁶⁶							
→If General anesthesia, Airway Management Method ¹⁵⁹⁴⁰ : ☐ Mask ☐ Endotracheal intubation ☐ Laryngeal mask airway							
(Select all that apply) ☐ Tracheostomy ☐ Previously intubated ☐ Not Documented ¹⁶²⁴¹							
Access Location ¹⁵⁰⁸⁹ : (Select all that apply) ☐ Venous ☐ Arterial							
Access Site ¹⁵⁸⁵³ : (Select all that apply) ☐ Brachial vein ☐ Femoral vein ☐ Hepatic vein ☐ Internal jugular vein ☐ Jugular vein							
☐ Subclavian vein ☐ Transthoracic ☐ Umbilical vein ☐ Other vein ☐ Axillary artery ☐ Brachial artery							
☐ Carotid artery ☐ Femoral artery ☐ Radial artery ☐ Umbilical artery ☐ Other artery							
Systemic Heparinization ¹⁵¹⁰² : ☐ No ☐ Yes →If Yes, ACT Peak ¹⁵¹⁰⁴ : _____ secs ☐ ACT not monitored ¹⁵⁸⁵¹							
→If Yes and ACT Not Monitored ¹⁵⁸⁵¹ = No, ACT Below Target ¹⁵⁸⁵⁰ : ☐ No ☐ Yes (Target as defined by the provider)							
☐ ACT below target not documented ¹⁵⁸⁵⁴							
Transfusion ¹⁶¹³⁰ : ☐ No ☐ Yes – Adverse event related ☐ Yes – Not adverse event related							
Echocardiography ¹⁶²⁰⁶ : ☐ No ☐ Yes – Intracardiac (ICE) ☐ Yes – Transthoracic (TTE) ☐ Yes – Transesophageal (TEE)							
Mechanical Ventricular Support ⁷⁴²² : ☐ No ☐ Yes → If Yes, Device ⁷⁴²³ : <u>Select from dynamic list</u>							
→ If Yes, Timing ⁷⁴²⁴ : ☐ In place at start of procedure ☐ Inserted during procedure and prior to intervention							
☐ Inserted after intervention begun							
HEMODYNAMICS (COMPLETE FOR DIAGNOSTIC OR INTERVENTIONAL CATHETERIZATION)							
Systemic Arterial Saturation ¹⁵¹²⁵ : _____ %							☐ Not Assessed ¹⁵¹⁰⁷
Cardiac index ¹⁵¹³⁶ : _____ L/min/m ²							☐ Not Assessed ¹⁵¹²³
RVSP: Systemic SBP Ratio ¹⁵⁸⁴² : _____							☐ Not Assessed ¹⁵⁸⁴³
Systemic Ventricular End Diastolic Pressure ¹⁵¹²⁸ : _____ mmHg							☐ Not Assessed ¹⁵¹¹⁵
Qp:Qs Ratio ¹⁵¹³⁷ : _____							☐ Not Assessed ¹⁵¹²⁴
Mixed Venous Saturation ¹⁵¹²⁶ : _____ %							☐ Not Assessed ¹⁵¹⁰⁸
Pulmonary Vascular Resistance Index ¹⁵¹³⁵ : _____ Wood units·m ²							☐ Not Assessed ¹⁵¹²²
Pulmonary Artery Mean Pressure ¹⁵¹³³ : _____ mmHg							☐ Not Assessed ¹⁵¹²⁰
IMAGING, RADIATION AND CONTRAST							
Contrast Volume ¹⁵⁸³⁸ : _____ mL							☐ Not Documented ¹⁵⁸⁹²
X-Ray Imaging Used ¹⁵¹¹² : ☐ No ☐ Yes - Single plane ☐ Yes - Biplane ☐ Yes - Rotational							
Fluoroscopy Used ¹⁵⁸³⁷ : ☐ No ☐ Yes							
→If Yes, Fluoroscopy Time ⁷²¹⁴ : _____ Minutes							
→If Yes, Cumulative Air Kerma ¹⁵²²⁵ : _____ O mGy ☐ Gy (Reference Air Kerma, Cumulative Dose, Reference Point Dose)							
→If Yes, Dose Area Product ¹⁵²²⁶ : _____ O Gy·cm ² ☐ dGy·cm ² ☐ cGy·cm ² ☐ mGy·cm ² ☐ μGy·M ²							



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COARCTATION OF THE AORTA INTERVENTION (COMPLETE IF PROCEDURE PERFORMED¹⁵⁰⁸¹ = COARCTATION INTERVENTION)

Primary Procedure Indication¹⁵²⁵⁵: ☐ Non-invasive gradient ☐ Systemic hypertension ☐ Exertional hypertension only
☐ Stenosis by imaging ☐ Systolic ventricular dysfunction

Prior Intervention At Lesion Site¹⁵⁸⁶⁹: ☐ No ☐ Yes – Catheterization ☐ Yes – Surgical ☐ Yes – Both

PRE-INTERVENTION

Peak Systolic Gradient¹⁵²⁶³: _____ mmHg

☐ Not Assessed¹⁵²⁶⁴

Minimal Lumen Diameter¹⁵²⁶¹: _____ mm

☐ Not Assessed¹⁵²⁶²

Distal Transverse Aortic Arch Diameter¹⁵⁸⁷⁵: _____ mm

☐ Not Documented¹⁵⁸⁷⁶

POST-INTERVENTION

Peak Systolic Gradient¹⁵²⁶⁷: _____ mmHg

☐ Not Assessed¹⁵²⁶⁸

Minimal Lumen Diameter¹⁵²⁶⁵: _____ mm

☐ Not Assessed¹⁵²⁶⁶

Gradient Attributable to Intervened Site¹⁵⁸⁷¹: _____ mmHg

☐ Not Documented¹⁵⁸⁷²

Balloon Dilation Only¹⁵⁸⁷⁰: ☐ No ☐ Yes

IF BALLOON DILATION ONLY (NO STENT IMPLANTATION) (BALLOON DILATION ONLY¹⁵⁸⁷⁰ = YES)

Initial Balloon Diameter¹⁵⁸⁷³: _____ mm

Final Balloon Diameter¹⁵⁸⁷⁴: _____ mm

Waist On Any Balloon¹⁵⁸⁷⁸: ☐ No ☐ Yes

→If Yes, Waist Resolved¹⁵⁸⁷⁹: ☐ No ☐ Yes

STENT IMPLANTATION (BALLOON DILATION ONLY¹⁵⁸⁷⁰ = No)

Indication For Stent Placement¹⁵⁸⁵⁸ (For the first stent) ☐ Primary Therapy ☐ Insufficient gradient relief after balloon dilation
☐ Treatment/stabilization of injury after balloon dilation

Balloon Diameter Immediately Preceding Stent Placement¹⁵⁸⁸⁰: _____ mm ☐ Not Assessed (Balloon not used)¹⁵⁸⁸¹

Waist On Any Balloon¹⁵⁸⁵⁹: ☐ No ☐ Yes ☐ Not Assessed (Balloon not used)¹⁵⁸⁶¹

→If Yes, Waist Resolved¹⁵⁸⁶⁰: ☐ No ☐ Yes

STENT COUNTER ¹⁵²⁷³	1	2 (Enter only the first two stents)
Stent ¹⁵²⁷⁴	(dynamic list of stents)	(dynamic list of stents)
UDI ¹⁵⁸⁶⁴	Future use	Future use
Length ¹⁵⁸⁶³	_____ O mm O cm	_____ O mm O cm
Diameter ¹⁵⁸⁸²	_____ O mm O cm	_____ O mm O cm
Stent Type Used ¹⁵⁸⁶²	☐ Bare metal ☐ Covered	☐ Bare metal ☐ Covered
Implanting Balloon Diameter ¹⁵⁸⁶⁵	_____ mm	_____ mm
Post Dilatation ¹⁵⁸⁶⁶ :	☐ No ☐ Yes	☐ No ☐ Yes
→If Yes, Post Dilatation Balloon Diameter ¹⁵⁸⁶⁷ :	_____ mm	_____ mm
Reason for Second Stent ¹⁵⁸⁷⁷ :		☐ Initial stent malposition ☐ Initial stent too short ☐ Initial stent recoil ☐ Vascular Injury

PROXIMAL PULMONARY ARTERY STENTING (COMPLETE IF PROCEDURE PERFORMED¹⁵⁰⁸¹ = PULMONARY ARTERY STENTING)
 (EXCLUDE BILATERAL CASES)

Primary Procedure Indication¹⁵²²⁷: ☐ Angiographic narrowing ☐ Right ventricular hypertension
 (Select all that apply) ☐ PA pressure gradient > 20 mmHg ☐ Right ventricular dysfunction
☐ Differential blood flow (<35% flow to lung of targeted vessel) ☐ Pulmonary valve regurgitation

☐ **Ostial Stenosis Present**¹⁶¹³² (If checked, do not answer Proximal Diameter^{15239/15247})

	Pre-intervention	Post-intervention
Proximal Diameter ^{15239/15247} :	_____ mm	_____ mm
Distal Diameter ^{15240/15248} :	_____ mm	_____ mm
Defect Diameter Minimum ^{15241/15250} :	_____ mm	_____ mm

STENT UTILIZATION	1	2 (Complete if a second stent was used)
Device Counter ¹⁵²⁵¹		
Stent(s) ¹⁵²⁵³	(dynamic list of stents)	(dynamic list of stents)
UDI ¹⁵⁹¹³	Future use	Future use
Length ¹⁵⁹¹¹	_____ O cm O mm	_____ O cm O mm
Diameter ¹⁵⁹¹²	_____ O cm O mm	_____ O cm O mm
Location ¹⁵²²⁹	O L Proximal O R Proximal	
Successful treatment ¹⁵⁹⁴¹ :	O No O Yes	
Stent Embolization ¹⁵⁹⁴² :	O No O Yes	
Stent Malposition ¹⁵⁹⁴³ :	O No O Yes	
Stent Overhang (Compromising access to contralateral PA) ¹⁵⁹¹⁴	O No O Yes	
Jailed side-branch (with compromised flow) ¹⁵⁹⁴⁴ :	O No O Yes	



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ATRIAL SEPTAL DEFECT CLOSURE (COMPLETE IF PROCEDURE PERFORMED¹⁵⁰⁸¹ = ATRIAL SEPTAL DEFECT CLOSURE)

Atrial Septal Defect (ASD) Classification ¹⁵⁸⁹³ :	☐ ASD - Simple	☐ ASD - Multiple	
☐ ASD with pulmonary artery hypertension	☐ ASD with pulmonary stenosis	☐ ASD with congenital heart disease	
Primary Procedure Indication ¹⁵¹⁴¹ :	☐ Failure to thrive	☐ Need for respiratory support	☐ Recurrent respiratory infections
	☐ Right-to-left cardiac shunt	☐ Right ventricular volume overload (RVVO)	

IMAGING INTRA-PROCEDURE (CODE BASED ON THE PRIMARY OR PREDOMINANT DEFECT)

ASD Dimension View 1 ¹⁵⁹⁰⁰ :	_____ mm	☐ Not documented ¹⁵⁹⁰¹
ASD Dimension View 2 ¹⁵⁹⁰² :	_____ mm	☐ Not documented ¹⁵⁹⁰³
Total Septal Length ¹⁵¹⁵⁶ :	_____ mm	☐ Not Assessed ¹⁵¹⁵⁷
Deficient Rim ¹⁵⁸⁹⁴ :	☐ No ☐ Yes	
→If Yes, Deficient Rim Length ¹⁵⁸⁹⁵ :	_____ mm	☐ Not documented ¹⁵⁸⁹⁸
→If Yes, Deficient Rim Location ¹⁶¹³³ :	(Select all that apply) ☐ Retroaortic ☐ Superior Vena Cava ☐ Posterior ☐ Inferior	
→If Yes, 2nd Deficient Rim ¹⁵⁸⁹⁶ :	☐ No ☐ Yes	
→If Yes, 2nd Deficient Rim Length ¹⁵⁸⁹⁷ :	_____ mm	☐ Not documented ¹⁵⁸⁹⁹

Atrial Septal Aneurysm Present¹⁵¹⁵⁸: ☐ No ☐ Yes

Balloon Sizing Performed¹⁵¹⁶²: ☐ No ☐ Yes

→If Yes, **Method**¹⁵⁹⁰⁸: (Select all that apply) ☐ Waist ☐ Stop Flow

DEVICE UTILIZATION ¹⁴⁸⁴²	1	2
Device(s) ¹⁵²⁰³ :	(Dynamic list of devices)	(Dynamic list of devices)
UDI (future use) ¹⁵⁹¹⁰ :	_____	_____

2nd Device Indication¹⁵⁹⁰⁹: (Complete if second device is used, select all that apply) ☐ Change size ☐ Unanticipated device problem ☐ Other

PATIENT OUTCOME

Residual Shunt Size¹⁵²⁰²: ☐ No shunt ☐ Trivial shunt (<3 mm) ☐ Significant shunt (>=3 mm)

AORTIC VALVULOPLASTY (COMPLETE IF PROCEDURE PERFORMED¹⁵⁰⁸¹ = AORTIC VALVULOPLASTY)

Primary Procedure Indication ¹⁵²⁰⁴ :	☐ Abnormal stress test/ECG	☐ Aortic valve gradient			
	☐ Left ventricular dysfunction	☐ Symptoms			
Aortic Valve Morphology ¹⁵²⁰⁹ :	☐ Unicuspid	☐ Bicuspid	☐ Tricuspid	☐ Quadricuspid	☐ Uncertain
Aortic Valve Annulus Diameter ¹⁵²¹² :	_____ mm				

Measurements Pre-Dilation

Pre-Intervention Aortic Valve Regurgitation¹⁵²¹¹: ☐ None ☐ 1+ (mild) ☐ 2+ (moderate) ☐ 3+ (moderate to severe) ☐ 4+ (severe)

Pre-Intervention Peak Aortic Valve Systolic Gradient¹⁵²²⁴: _____ mmHg ☐ Not documented¹⁵⁸⁴⁰

Measurements Post-Intervention

Post-Intervention Aortic Valve Regurgitation¹⁵²²²: ☐ None ☐ 1+ (mild) ☐ 2+ (moderate) ☐ 3+ (moderate to severe) ☐ 4+ (severe)

Post-Intervention Peak Systolic Gradient¹⁵²²³: _____ mmHg ☐ Not documented¹⁵⁸⁴¹

DEVICE UTILIZATION

Balloon Technique¹⁵²¹³: ☐ Single ☐ Double **Balloon Diameter (largest)**¹⁵⁸³⁹: _____ mm

Balloon Stabilization¹⁵²¹⁹: ☐ No ☐ Yes



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PATENT DUCTUS ARTERIOSUS (PDA) CLOSURE (COMPLETE IF PROCEDURE PERFORMED¹⁵⁰⁸¹ = PREMATURE INFANT PDA CLOSURE)
(PREMATURE INFANT IS DEFINED AS 24-37 WEEKS PRE-TERM OR 700 – 2500 GRAMS)

RESPIRATORY STATUS

Respiratory Support¹⁶¹³¹: ☐ No ☐ Yes

→If Yes, **Respiratory Support Type**¹⁵⁹¹⁸: ☐ Continuous positive airway pressure (CPAP) ☐ Conventional ventilation
☐ High-flow nasal cannula (HFNC) ☐ High-frequency oscillatory ventilation (HFOV)
☐ Jet ventilation (JET) ☐ Other

Mean Airway Pressure (MAP)¹⁵⁹²⁸: _____ cmH2O ☐ Not Assessed¹⁵⁹²⁹

Fraction of Inspired Oxygen (FiO2)¹⁵⁹²⁶: _____ % ☐ Not Assessed¹⁵⁹²⁷

Respiratory Severity Score¹⁵⁹²¹: _____ ☐ Not Assessed¹⁵⁹²²

MEDICATION

Inotrope Administered¹⁵¹⁰⁵: ☐ No ☐ Yes

INTRA-PROCEDURE

Procedure Location¹²⁸⁷¹: ☐ Cath lab ☐ Bedside/NICU ☐ Other

PDA Morphology¹⁵²⁸⁵: ☐ Type - A ☐ Type - B ☐ Type - C ☐ Type - D ☐ Type - E ☐ Type - F

Aortic Ampulla Dimension¹⁵²⁸²: _____ mm

Minimum Diameter¹⁵²⁸³: _____ mm

PDA Length¹⁵²⁸⁴: _____ mm

Measurement Technique¹⁵⁹³⁰: ☐ Angiography ☐ Echocardiography

Tricuspid Regurgitation (Pre-closure)¹⁵⁹²⁴: ☐ None ☐ Trace/Trivial ☐ Mild ☐ Moderate ☐ Mod - severe ☐ Severe

Ductal Angiography¹⁵⁹³¹: ☐ No ☐ Yes

PDA Closure Device Counter ¹⁵⁹⁶⁵	1 (If more than one device is used, enter only the initial device and the final device)	2
Catheter Technique ¹⁵⁹³² :	☐ Balloon endhole ☐ Directional endhole with microcatheter, 0.014 wire ☐ Directional endhole with 0.035 wire ☐ Other	☐ Balloon endhole ☐ Directional endhole with microcatheter, 0.014 wire ☐ Directional endhole with 0.035 wire ☐ Other
Device Used For Closure ¹⁵²⁹⁰	<u>Select from device list</u>	<u>Select from device list</u>
UDI ¹⁵⁹²³	(Future use)	(Future use)
Waist Diameter ¹⁵⁹³⁴	_____ mm	_____ mm
Disc Diameter ¹⁵⁹³⁵	_____ mm	_____ mm
Length ¹⁵⁹³⁶	_____ mm	_____ mm
Implant Technique ¹⁵⁹²⁰	☐ Antegrade (from venous access) ☐ Retrograde (from arterial access)	☐ Antegrade (from venous access) ☐ Retrograde (from arterial access)
Device Outcome ¹⁵²⁹¹ :	☐ Device in place ☐ Device removed by catheter ☐ Intra-operative removal ☐ Unknown	☐ Device in place ☐ Device removed by catheter ☐ Intra-operative removal ☐ Unknown

OUTCOME

Post Procedure Obstruction¹⁵⁹³³: (Select all that apply) ☐ Aorta ☐ Pulmonary artery ☐ No obstruction ☐ Not Assessed¹⁶²⁴²

Tricuspid Valve Regurgitation (Post-closure)¹⁵⁹¹⁹: ☐ None ☐ Trace/Trivial ☐ Mild ☐ Moderate ☐ Mod-severe ☐ Severe

Residual Shunt¹⁵²⁸⁸: ☐ None ☐ Trace/Trivial ☐ Mild ☐ Moderate ☐ Severe



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TRANSCATHETER PULMONARY VALVE REPLACEMENT (COMPLETE IF PROCEDURE PERFORMED¹⁵⁰⁸¹ = TRANSCATHETER PULMONARY VALVE REPLACEMENT)

Clinical Indication¹⁵²⁹³: (Select all that apply) ☐ Arrhythmia ☐ Symptomatic ☐ Ventricular function decline ☐ Right ventricle dilation

Hemodynamic Indication¹⁵²⁹⁴: ☐ Predominant valve/conduit obstruction ☐ Predominant valve/conduit regurgitation
☐ Mixed obstruction and regurgitation

Prior Right Ventricular Outflow tract (RVOT) Treatment¹⁶¹⁵⁴: ☐ Prior balloon angioplasty ☐ Prior RVOT stent
☐ Prior transannular patch ☐ Prior surgical valvotomy ☐ Prior RV-PA conduit
☐ Prior surgical bioprosthesis ☐ Prior TPVR ☐ None

→If Prior Surgical Bioprosthesis, **Bioprosthesis Type**¹⁶¹⁵⁸: ☐ Pulmonary homograft ☐ Aortic homograft ☐ Porcine ☐ Bovine
(Select all that apply) ☐ Synthetic ☐ Other

→If Prior Surgical Bioprosthesis, **Bioprosthesis Size**¹⁵³¹¹: _____ mm

TPVR - IMAGING PRE-PROCEDURE

Echocardiogram¹⁵²⁹⁶: ☐ No ☐ Yes

→If Yes, **LVEF**¹⁵³⁰¹: _____ % ☐ Not Assessed¹⁶¹⁵⁷

→If Yes, **Mean Pulmonary Valve/Conduit Gradient**¹⁵²⁹⁷: _____ mmHg ☐ Not Assessed¹⁶¹⁶⁸

→If Yes, **Maximum Pulmonary Valve/Conduit Gradient**¹⁵²⁹⁸: _____ mmHg ☐ Not Assessed¹⁶¹⁴⁵

→If Yes, **Pulmonary Valve Regurgitation**¹⁵²⁹⁹: ☐ None ☐ Mild ☐ Moderate ☐ Mod-severe ☐ Severe

→If Yes, **Tricuspid Valve Regurgitation**¹⁵³⁰⁰: ☐ None ☐ Mild ☐ Moderate ☐ Mod-severe ☐ Severe

MRI¹⁵³⁰²: ☐ No ☐ Yes

→If Yes, **RVEF**¹⁵³⁰³: _____ % ☐ Not Assessed¹⁶¹⁴⁷

→If Yes, **PR Fraction**¹⁵³⁰⁵: _____ % ☐ Not Assessed¹⁶¹⁴⁶

→If Yes, **RVEDV Index**¹⁵³⁰⁶: _____ ml/m² ☐ Not Assessed¹⁶¹⁵¹

VALVE/CONDUIT INTRA-PROCEDURE HEMODYNAMIC MEASUREMENTS

Peak Gradient Across Valve/Conduit¹⁵³¹⁴: _____ mmHg ☐ Not Assessed¹⁶¹⁶³

Narrowest Valve/Conduit Diameter¹⁵³¹⁵: _____ mm ☐ Not Assessed¹⁶¹⁶⁴

VALVE TYPE

Valve Type¹⁶¹⁴⁴: ☐ Balloon expandable ☐ Self expanding

BALLOON EXPANDABLE VALVE (VALVE TYPE¹⁶¹⁴⁴ = BALLOON EXPANDABLE)

Coronary Compression Testing Performed¹⁵³¹⁸: ☐ No ☐ Yes

→If Yes, **Coronary Compression Present**¹⁵³²⁰: ☐ No ☐ Yes ☐ Uncertain

→If Yes, **Impact On Case**¹⁶¹⁶⁰: ☐ Valve not implanted ☐ Implanted with technical modification

Pre-dilation Performed¹⁵²⁹²: ☐ No ☐ Yes

→If Yes, **First Balloon size**¹⁵³²¹: _____ mm

→If Yes, **Maximum Balloon size**¹⁵³²²: _____ mm

TRANSCATHETER PULMONARY VALVE REPLACEMENT (CONT.)
TRANSCATHETER PULMONARY VALVE REPLACEMENT – DEVICE COUNTER¹⁵³³⁹

	TPVR Device(s) ¹⁵³⁴⁰	Valve Diameter ¹⁶¹⁶¹	Valve Stability ¹⁶¹⁶²	Implanted In Intended Location ¹⁶¹⁵⁶	UDI ¹⁶¹⁵⁰
1	_____	_____ mm	☐ Stable frame ☐ Unstable frame	☐ No ☐ Yes – Supra-annular implant ☐ Yes – Annular implant	Future use
2	_____	_____ mm	☐ Stable frame ☐ Unstable frame	☐ No ☐ Yes – Supra-annular implant ☐ Yes – Annular implant	Future use

VALVE DEPLOYED

Transcatheter Pulmonary Valve (TPV) Deployed¹⁵³³¹: ☐ No ☐ Yes

→If Yes, **Post-implant Peak RVOT Gradient**¹⁵³³⁵: _____ mmHg ☐ Not Assessed¹⁶¹⁵²

→If Yes, **Pulmonary Valve Central Regurgitation**¹⁵³³⁶: ☐ None ☐ Mild ☐ Moderate ☐ Mod-severe ☐ Severe

→If Yes, **Perivalvular Pulmonary Regurgitation**¹⁶¹⁵⁹: ☐ None ☐ Mild ☐ Moderate ☐ Mod-severe ☐ Severe

→If No, **Reason TPV Not Deployed**¹⁵³³⁸:

☐ Coronary artery compression risk ☐ Valve could not be advanced to implant location ☐ Complication before deployment

☐ Pre-stent implanted, electively staged TPVR ☐ No treatable landing zone ☐ Other

☐ Device/Delivery system dysfunction/complication

VALVE DEPLOYED¹⁵³³¹ = YES AND VALVE TYPE¹⁶¹⁴⁴ = **BALLOON EXPANDABLE VALVE**

Delivery Balloon Size¹⁵³³⁰: _____ mm

TPVR – NON-INVASIVE IMAGING POST-PROCEDURE (TIMEFRAME: POST-PROCEDURE TO DISCHARGE)

Post-Procedure Echocardiogram¹⁵³⁴²: ☐ No ☐ Yes

→If Yes, **Maximum Gradient Across Valve/Conduit**¹⁵³⁴⁴: _____ mmHg ☐ Not Assessed¹⁶¹⁴⁹

→If Yes, **Mean Gradient Across Valve/Conduit**¹⁵³⁴³: _____ mmHg ☐ Not Assessed¹⁶¹⁴⁸

→If Yes, **Pulmonary Valve Central Regurgitation**¹⁵³⁴⁵: ☐ None ☐ Mild ☐ Moderate ☐ Mod-severe ☐ Severe ☐ Not Assessed¹⁶¹⁵³

→If Yes, **Perivalvular Regurgitation**¹⁶²¹⁹: ☐ None ☐ Mild ☐ Moderate ☐ Mod-severe ☐ Severe

NON-MODULE INTERVENTION (COMPLETE IF PROCEDURE PERFORMED¹⁵⁰⁸¹ = NON-MODULE INTERVENTION)
NON-MODULE INTERVENTION COUNTER¹⁶²¹⁶

	Specific Procedure(s) Performed ¹⁵⁰⁶⁷	Counter ¹⁶²⁸⁷	Device(s) Used ¹⁵⁹³⁷	UDI ¹⁵⁹³⁸
1	_____	1	_____	Future use
		2	_____	
		3	_____	
2	_____	1	_____	Future use
		2	_____	
		3	_____	



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INTRA- AND POST-PROCEDURE EVENTS (COMPLETE FOR EACH LAB VISIT)

EVENT(S) ¹⁵¹⁵³	EVENT(S) OCCURRED ¹⁵²⁰⁷	→ IF YES
Access site (At any access site selected Access Site ¹⁵⁸⁵³)		
Arteriovenous fistula requiring treatment	☐ No ☐ Yes	
Closure device related injury (access site)	☐ No ☐ Yes	
Hematoma at access site	☐ No ☐ Yes	
Pseudoaneurysm requiring treatment	☐ No ☐ Yes	
Pulse loss requiring treatment	☐ No ☐ Yes	
Rebleed after bandaging	☐ No ☐ Yes	
Sheath related intimal injury	☐ No ☐ Yes	
Thrombosis (at access site)	☐ No ☐ Yes	
		Thrombosis Type¹⁵⁹⁵¹: (Select all that apply) ☐ Venous ☐ Arterial
Anesthesia		
Aspiration of gastric contents	☐ No ☐ Yes	
Broncho/laryngospasm while intubated	☐ No ☐ Yes	
Conscious sedation req. rescue intubation	☐ No ☐ Yes	
Corneal abrasion	☐ No ☐ Yes	
Delirium	☐ No ☐ Yes	
Dental injury	☐ No ☐ Yes	
Endotracheal tube malposition	☐ No ☐ Yes	
Lung collapse	☐ No ☐ Yes	
Malignant hyperthermia- hyperpyrexia	☐ No ☐ Yes	
Post extubation stridor	☐ No ☐ Yes	
Oral/airway Injury or bleeding	☐ No ☐ Yes	
Unanticipated difficult airway	☐ No ☐ Yes	
Unplanned extubation	☐ No ☐ Yes	
Angioplasty (Complete for angioplasty related events (Coarctation, Proximal pulmonary artery stenting, Aortic valvuloplasty, NMI))		
Aneurysm (angioplasty related)	☐ No ☐ Yes	
Contained tear req. treatment (angioplasty)	☐ No ☐ Yes	
Tear/dissection	☐ No ☐ Yes	
Thrombosis (at target site)	☐ No ☐ Yes	
Angioplasty related vessel/conduit rupture	☐ No ☐ Yes	
		Flow Obstruction¹⁵⁹⁵²: ☐ No ☐ Yes

INTRA AND POST-PROCEDURE EVENTS (COMPLETE FOR EACH LAB VISIT)

EVENT(S) ¹⁵¹⁵³	EVENT(S) OCCURRED ¹⁵²⁰⁷	→ IF YES
Cardiac		
Arrhythmia requiring treatment (e.g. pharmacologic therapy, DCCV, temporary or permanent pacing)	O No O Yes	Arrhythmia Type¹⁵⁹⁴⁹: (Select all that apply) ☐ Atrial fibrillation ☐ Atrial flutter ☐ 1 st degree AV block ☐ 2 nd degree AV block ☐ 3 rd degree AV block ☐ Bradycardia requiring intervention ☐ Persistent bundle branch block
Cardiac arrest	O No O Yes	Cardiac Arrest Etiology¹⁵⁹⁵⁵: (Select all that apply) ☐ Supraventricular tachycardia ☐ Ventricular fibrillation ☐ Ventricular tachycardia ☐ Complete heart block ☐ Pulseless Electric Activity (PEA) ☐ Acute hemorrhage ☐ Coronary ischemia ☐ Cardiac tamponade ☐ Progressive low cardiac output ☐ Pulmonary hypertensive crises ☐ Respiratory arrest ☐ Etiology unknown ¹⁶²⁴⁸
Cardiac perforation	O No O Yes	Biopsy Related¹⁵⁹⁵³: O No O Yes
Cardiac tamponade	O No O Yes	
Coronary vasospasm requiring treatment	O No O Yes	
Mechanical circulatory support required	O No O Yes	
Pacemaker or ICD Implant Due to Cath Complication	O No O Yes	
Pericardial effusion	O No O Yes	
New Aortic valve insufficiency	O No O Yes	Biopsy Related¹⁵⁹⁵⁴: O No O Yes
New Tricuspid valve insufficiency	O No O Yes	
New Mitral valve insufficiency	O No O Yes	
New Pulmonary valve insufficiency	O No O Yes	
New or exacerbation of heart failure	O No O Yes	
Coil or Device (Complete for cases involving coils or non-stent devices)		
Coil embolization	O No O Yes	Coil Retrieved¹⁵⁹⁵⁶: O No O Yes
Coil malposition	O No O Yes	
Device embolization	O No O Yes	Device Retrieved¹⁵⁹⁴⁵: O No O Yes
Device malposition	O No O Yes	Blood Flow Obstruction¹⁵⁹⁴⁶: O No O Yes

INTRA AND POST-PROCEDURE EVENTS (COMPLETE FOR EACH LAB VISIT)

EVENT(S) ¹⁵¹⁵³	EVENT(S) OCCURRED ¹⁵²⁰⁷	→ IF YES
General		
Allergy – contrast	☐ No ☐ Yes	
Allergy – medication	☐ No ☐ Yes	
Air embolus in systemic circulation	☐ No ☐ Yes	
Air embolus in venous/pulmonary circulation	☐ No ☐ Yes	
Bacteremia (post-catheterization)	☐ No ☐ Yes	
Complication of bladder catheterization	☐ No ☐ Yes	
Fall	☐ No ☐ Yes	
Gastrointestinal bleeding	☐ No ☐ Yes	
Hypoglycemia	☐ No ☐ Yes	
Hypothermia	☐ No ☐ Yes	
Medication error	☐ No ☐ Yes	
Necrotizing enterocolitis	☐ No ☐ Yes	
New requirement for dialysis	☐ No ☐ Yes	
Pressure injury	☐ No ☐ Yes	
Post procedure fever > 38C	☐ No ☐ Yes	
Radiation exposure injury	☐ No ☐ Yes	
Retained foreign body	☐ No ☐ Yes	
Retroperitoneal bleeding	☐ No ☐ Yes	
Retroperitoneal hematoma	☐ No ☐ Yes	
Skeletal trauma/injury	☐ No ☐ Yes	
Transfusion reaction	☐ No ☐ Yes	
Neurologic		
Brachial plexus injury	☐ No ☐ Yes	Stroke Type¹⁵⁹⁴⁷: ☐ Hemorrhagic ☐ Ischemic ☐ Undetermined
Seizures (new onset)	☐ No ☐ Yes	
Spinal cord ischemia	☐ No ☐ Yes	
Stroke	☐ No ☐ Yes	
Transient ischemic attack	☐ No ☐ Yes	
Pulmonary		
Hemothorax	☐ No ☐ Yes	
Pneumonia	☐ No ☐ Yes	
Pneumothorax	☐ No ☐ Yes	
Pulmonary embolism	☐ No ☐ Yes	
Pulmonary hemorrhage	☐ No ☐ Yes	
Reperfusion injury	☐ No ☐ Yes	



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INTRA AND POST-PROCEDURE EVENTS (COMPLETE FOR EACH LAB VISIT)

EVENT(S) ¹⁵¹⁵³	EVENT(S) OCCURRED ¹⁵²⁰⁷	→ IF YES
Stent		
Bronchial compression	☐ No ☐ Yes	
Contained tear requiring treatment	☐ No ☐ Yes	
Coronary compression	☐ No ☐ Yes	
Jailing of side branch resulting in compromised flow	☐ No ☐ Yes	
Stent malposition	☐ No ☐ Yes	
Stent embolization	☐ No ☐ Yes	
Stent thrombosis	☐ No ☐ Yes	
Stent related vessel/conduit rupture	☐ No ☐ Yes	
Vascular compression – other adjacent vessel	☐ No ☐ Yes	

Vascular Injury

Coronary artery dissection	☐ No ☐ Yes	Intervention Site Thrombosis Type¹⁵⁹⁴⁸: ☐ Venous ☐ Arterial (Select all that apply)
Thrombus (Intervention site)	☐ No ☐ Yes	
Vascular dissection (Vessel other than coronary artery)	☐ No ☐ Yes	
Vascular perforation (Vessel other than coronary artery)	☐ No ☐ Yes	

POST-PROCEDURE TREATMENTS (COMPLETE FOR DIAGNOSTIC OR INTERVENTIONAL CATHETERIZATION)

INTRA- OR POST-PROCEDURE TREATMENT ¹⁵¹⁷¹	OCCURRED ¹⁵²⁰⁸	→IF YES
Cardiac surgery – Planned	☐ No ☐ Yes	
Cardiac surgery – Unplanned due to cath complication	☐ No ☐ Yes	
Subsequent cardiac cath due to cath complication	☐ No ☐ Yes	
Vascular surgery – Unplanned due to cath complication	☐ No ☐ Yes	
Other surgery - Unplanned	☐ No ☐ Yes	Due to Cath Complication¹⁵¹⁷²: ☐ No ☐ Yes

DISCHARGE

Discharge Date/Time¹⁰¹⁰¹ MM / DD / YYYY HH:MM

Discharge Status¹⁰¹⁰⁵: ☐ Alive ☐ Deceased

→ If Deceased, **Death in Lab¹⁰¹²⁰:** ☐ No ☐ Yes

→ If Deceased, **Cause of Death¹⁰¹²⁵:** ☐ Cardiac ☐ Non-Cardiac ☐ Undetermined